

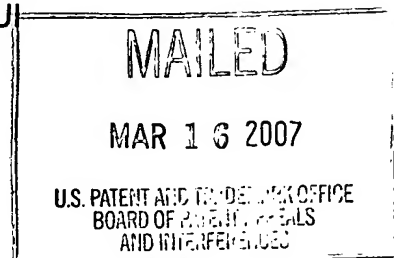
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte YOSHIMI KIKUCHI, MASAYO DATE,
YUKIKO UMEZAWA, KEIICHI YOKOYAMA
HARUO HEIMA, and HIROSHI MATSUI

Appeal No. 2006-3084
Application No. 10/673,860

ON BRIEF



Before SCHEINER, ADAMS, and GRIMES Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 3, 4, 7, 8, 10 and 11. Claims 5, 6, 9 and 12, the only remaining pending claims, were withdrawn from consideration as drawn to a non-elected invention.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A method for producing a heterologous protein comprising
 - A) culturing a Corynebacterium glutamicum AJ12036 (FERM BP-734) bacterium or mutant thereof having a genetic expression construct comprising a nucleic acid sequence encoding a signal peptide region from a coryneform bacterium which is downstream of a promoter sequence which functions in a

coryneform bacterium, and a nucleic acid sequence encoding a heterologous protein which is downstream of said nucleic acid sequence encoding said signal peptide region, []and

B) recovering said heterologous protein,

wherein said bacterium or mutant thereof is able to secrete the heterologous protein at least 2-fold higher than Corynebacterium glutamicum ATCC13869 having said genetic expression construct.

No prior art is relied upon by the examiner.

GROUND OF REJECTION

Claims 1, 3, 4, 7, 8, 10 and 11 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written descriptive support.

CLAIM CONSTRUCTION

Claim 1 is the only independent claim on appeal and is representative of the claimed subject matter. Claim 1 is drawn to a method for producing a heterologous protein. This method comprises two steps: (1) culturing a Corynebacterium glutamicum AJ12036 (FERM BP-734) bacterium or mutant thereof; and (2) recovering said heterologous protein. Claim 1 also places three requirements on the AJ12036 bacterium or mutant thereof. First, the AJ12036 bacterium or mutant thereof has a genetic expression construct comprising a nucleic acid sequence encoding a signal peptide region from a coryneform bacterium which is downstream of a promoter sequence which functions in a coryneform bacterium. Second, the AJ12036 bacterium or mutant thereof has a nucleic acid sequence encoding a heterologous protein which is downstream of

said nucleic acid sequence encoding said signal peptide region. Third, the AJ12036 bacterium or mutant thereof is able to secrete the heterologous protein at least 2-fold higher than the wild type Corynebacterium glutamicum ATCC13869 having said genetic expression construct.

DISCUSSION

According to the examiner (Answer, page 6), appellants' specification provides adequate written descriptive support for methods that use strain AJ12036. Nevertheless, the examiner finds (Answer, bridging sentence, pages 5-6) that appellants' disclosure is not "descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the methods utilizing the encompassed mutant coryneform bacteria, based on the teachings of the specification." As we understand it, the examiner's concern is focused solely on the aspect of appellants' claim relating to a mutant Corynebacterium glutamicum AJ12036 (FERM BP-734) bacterium.

In this regard, the examiner finds (Answer, page 4), "[t]he specification discloses that mutants may include any strains obtained by mutagenesis and selection procedures for increased secretory properties (page 10 of the specification)." While this is true, appellants' claimed invention is not directed to any mutated strain. Instead, as appellants explain (Brief, page 9), the claimed invention is directed to the use of Corynebacterium glutamicum AJ12036 (FERM BP-734) bacterium which has the ability to secrete heterologous protein at least

2-fold higher than ATCC13869¹, and “AJ12036-derived strains which have retained this activity, but otherwise might not be identical, i.e. mutants.” The examiner agrees, but remains of the opinion “that there is not an adequate description of the mutant strains that are encompassed.” Answer, page 7, emphasis removed.

The examiner acknowledges that the issue is not “[t]he ability to isolate, or discover, new mutants of the AJ12036 strain” Id. Instead, the examiner contends (id.) that AJ12036 mutants “which retain the ability of the parent strain to have increased secretion of proteins, therefore, have not been described in terms of their genetic structure.” Id. According to the examiner, since

[o]ne of skill in the art cannot envision the genetic alterations which would leave intact this ability to secrete proteins at a higher level than a wild type strain . . . [o]ne would not be able to envision the identity of such mutants, since one does not even know the starting structure, i.e. the genetic sequence or alteration responsible for the activity of increased secretion in AJ12036, from which mutants are derived.

Id. We disagree. As the examiner recognizes, methods of making mutants are known in the art and appellants’ claimed mutants are derived from the deposited Corynebacterium glutamicum AJ12036 (FERM BP-734). Therefore, the starting structure, i.e. the genetic sequence or alteration responsible for the activity of increased secretion, is defined by the deposited microorganism. As appellants explain (Reply Brief, page 3), “[t]here is no requirement to ‘envision’ the structure of the mutant since it has been deposited.” As set forth in Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 965, 63 USPQ2d 1609, 1614 (Fed. Cir. 2002),

¹ According to appellants’ specification (paragraph 27), Corynebacterium glutamicum AJ12036 (FERM BP-734) bacterium “has the capacity of secretory production of heterologous proteins at least 2-3 fold higher than the parent strain (wild type strain)”

"[w]hile deposit in a public depository most often has pertained to satisfaction of the enablement requirement, we have concluded that reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material."

As discussed above, the examiner agrees that appellants' specification provides adequate written descriptive support for a method utilizing the deposited Corynebacterium glutamicum AJ12036 (FERM BP-734) bacterium. The only issue is whether appellants' specification provides adequate written descriptive support for mutants of this bacterium which retain the ability to secrete a heterologous protein at least 2-fold higher than the wild type Corynebacterium glutamicum ATCC13869 having said genetic expression construct. In our opinion, appellants' specification provides adequate written descriptive support for these mutants.

As appellants explain (Brief, page 10), the phrase "mutant thereof" refers to a mutant of A12036 and as required by the claimed invention, this mutant must secrete a heterologous protein at least 2-fold higher than the wild type Corynebacterium glutamicum ATCC13869 having said genetic expression construct. Further, as appellants explain (Reply Brief, page 3), only those mutations "which do not disrupt the ability of the cell to secrete the heterologous protein 2-fold . . . [higher] than ATCC13869, are encompassed within the scope of the claims." Stated differently, appellants' claimed invention is directed to the use of Corynebacterium glutamicum AJ12036 (FERM BP-734) bacterium which has the ability to secrete heterologous protein at least 2-fold higher than

ATCC12869, and “AJ12036-derived strains which have retained this activity, but otherwise might not be identical, i.e. mutants.” Brief, page 9. In our opinion, appellants’ specification provides an adequate written description of the claimed invention.

Therefore, we reverse the rejection of claims 1, 3, 4, 7, 8, 10 and 11 under the written description provision of 35 U.S.C. § 112, first paragraph.

REVERSED

100-27-1026
 Eric R. Schreiner

Toni R. Scheiner
Administrative Patent Judge

Paul E Harris

Donald E. Adams
Administrative Patent Judge

Ed. Gri.

Eric Grimes
Administrative Patent Judge

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